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CRA Quarterly Progress Report: 01/01/2023 – 03/31/2023

Pragmatic Trial of Cannabidiol and Tailored Cannabis Coaching to Improve Chronic Pain Symptoms

Kevin F. Boehnke, PhD, Lead Principal Investigator
Rachel Bergmans, PhD, Co-Principal Investigator
Amy Bohnert, PhD, Co-Principal Investigator

1. **Percent of completion of the project objectives. This should include a brief outline of the work accomplished during the reporting period and the work to be completed during the subsequent reporting period.**

   We are still in startup and have made considerable progress in the last three months of this award. Activities include:

   Meetings:
   - We continue to conduct weekly meetings with the study PIs (Drs. Boehnke, Bohnert, and Bergmans) and program managers to coordinate all portions of this large study and resolve any issues that arise each week. The team has expanded to include the lead study coordinator and the health coaches.
   - Weekly meetings with the development and management team at CareEvolution to ensure proper build of the MIVetsCan study within MyDataHelps, the electronic data capture system that is available via web browser or smartphone app.
   - Veteran Engagement Research Council (VREC) Meeting – Monday, 3/13/2023: Dr. Boehnke was a guest presenter at the March VREC meeting, providing updates on project progress and community engagement.
   - Community Advisory Board (CAB) Meeting – Thursday, 3/16/2023: This was the first formal CAB meeting where we brought together Veterans with chronic pain, clinicians, and pain researchers to discuss the project. We have also had numerous ad hoc meetings with Veteran partners to make connections with the community and gain insights and gather feedback for various aspects of the project.

   Personnel:
   - Study Coordinators: A full-time study coordinator was hired in January 2023. The study coordinator will assist in all aspects of the project: recruitment, regulatory, retention, engagement, and oversight of the trials. The team also engaged another study coordinator working within the VA Ann Arbor system to focus on regulatory affairs within the VA and to assist in recruitment efforts.
   - Lead Health Education Coach: The position was posted in December 2022, with successful hire of the health coach in March 2023. The team has also engaged an

additional health coach that will assist the Lead in delivering the educational intervention. Both health coaches have experience in research, Motivational Interviewing, and backgrounds in social work to help participants optimize their cannabis use to improve pain symptoms. The behavioral health coaches will also aid with retention and study coordination efforts related to the participants with whom they are directly working in this study.

- Communications Specialist: The team hired a consultant/graphic designer to assist with developing materials for dissemination and marketing. The graphic designer has aided in branding the project and work by the UM team, beginning development of the public-facing website, and creating infographics that will eventually be used during the education intervention.

Regulatory:

- The team worked with the Michigan Investigator Assistance Program (MIAP) at University of Michigan, which handles Investigational New Drug (IND) submission to the Food and Drug Administration (FDA) to prepare and submit the IND application to pilot the CBD Trial (CBD-Care) and Behavioral Intervention (Can-Coach) in the first half of 2023. The IND application was submitted to the FDA in February 2023, whose review resulted in a clinical hold on the CBD-Care trial. The team is awaiting written and electronic feedback regarding the IND application review and is expected to receive the feedback in April 2023, at which point we can respond to the FDA's comments in their clinical hold letter.
    - The Can-Coach protocol description was included in the IND, and FDA determined that this intervention does not require FDA oversight. The team is proceeding with the behavioral intervention development, approvals, and launch, beginning with a feasibility pilot slated for late spring/early summer.
- MIVetsCan Pain Registry Protocol: The Registry protocol was developed and approved by the UM IRBMed on Tuesday, 3/28/2023. This is the entry point to the project and then Veterans can enroll in both trials when they become available.
    - While the Registry is approved at UM, the team is also pursuing VA regulatory approval to assist with recruitment, data collection via medical records, and retention.
- Can-Coach/Behavioral Intervention Protocol: The protocol underwent further refinement during this period to prepare for the IRB application. The team will pursue a feasibility pilot study (n=20) for the education intervention to test the coaching sessions and understand the best approaches to most effectively deliver the sessions and collect survey data. The feasibility pilot is expected to enroll up to 20 participants to reach data saturation to inform the full trial, with launch expected in late 2023.

Veteran and Community Engagement:

- **Interview Study:** To ensure that our behavioral intervention is informed by Veteran voices and current Veteran experiences with medical cannabis, the team conducted a qualitative study of Veterans interested in or currently using medical cannabis.

  The initial goal for the interview study was to enroll up to 50 Veteran participants if needed. As of 3/31/2023, we have enrolled and interviewed 32 Veterans and have reached data saturation. We are no longer recruiting for this part of the project and will move on to data analysis with the goal of publishing important findings.

- **Community Advisory Board:** The team recruited several Veterans and community organizers/members who make up the Veterans/MIVetsCan Community Advisory Board (CAB). The members include six women and four men, who have a range of experience in the military, social work, and a passion for helping to improve the lives of Veterans in some capacity. The CAB members will assist with providing input from veterans with chronic pain, review project materials, and provide guidance on approaches to connecting and engaging the Veteran community to help improve chronic pain. The CAB members are compensated for their involvement and expertise. The first CAB meeting was held in March, with monthly meetings expected in the beginning of the project, and eventually move to bi-monthly or quarterly meetings.

2. Brief description of problems or delays, real or anticipated, which should be brought to the attention of the Grant Administrator.

- The IND application for the CBD trial was put on clinical hold. The study team had anticipated start of the trial sometime this summer. We are uncertain whether this will result in delays and will keep the Grant Administrator closely apprised of the unfolding situation. The team is awaiting feedback from the FDA in order to address any concerns and continue forward with the CBD trial.

3. Statement concerning any significant deviation from previously agreed-upon Statement of Work.

- Education Intervention Feasibility Pilot: The feasibility pilot was not explicitly described in the previously agreed upon Statement of Work, but it is an essential part of the intervention development. This pilot will help ensure that coaching sessions are appropriate and developed to assist Veterans gain knowledge and confidence in their cannabis use to effectively reduce their chronic pain. The team anticipates recruiting 20 Veterans in this pilot, which will very closely resemble the full Can-Coach Intervention. Work is currently underway on project materials such as surveys, recruitment materials, participant communications, and building items in MyDataHelps, REDCap, and other systems for the study activity.

4. Financial expenditures of grant money and other contributions to the project, in- kind and/or direct funding.

Funds were expended for personnel time and associated fringe benefits, consultant costs, social media advertising, Fitbits for our pilot study, fees for IND submission and transcriptions of interviews, and subject incentives for the qualitative interview study.

$103,432 – Direct Costs for Q1	$166,353 – Cumulative Direct Costs
10,113 – Indirect Costs at 9.77%	16,250 – Cumulative Indirect Costs
$113,545 – Total Q4 Expenditures	$182,603 – Cumulative Expenditures

We look forward to continued progress on this project over the next quarter.

Sincerely,
Kevin F. Boehnke, PhD
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